REMARKS

Claims 1 – 19 are pending in the application. Claims 4 – 7, 10, and 12 - 14 have been cancelled. Claims 1 and 11 have been amended. New claim 20 has been added. No new matter has been added by virtue of these amendments; support therefore can be found throughout the specification and original claims of the application.

Any cancellation of the claims should in no way be construed as acquiescence to any of the Examiner's rejections and was done solely to expedite the prosecution of the application. Applicant reserves the right to pursue the claims as originally filed in this or a separate application(s).

Rejection of Claims 1 – 3, 6 – 7, 11 – 12 and 15 - 19 under 35 U.S.C. 102(b)

Claims 1, 8 – 9 and 5 - 19 were rejected under 35 U.S.C. §102(b) as being anticipated by Minetoki et al. (Appl Microbiol Biotechnol, 1998: 50 p.459 – 467).

Applicants respectfully traverse the rejection.

Present claim 1 is directed to a modified Taka-amylase promoter from *Aspergillus oryzae* constructed by inserting a first DNA fragment including CCAATNNNNNN (a first base sequence: SEQ ID NO: 1) and a second DNA fragment including CGGNNNNNNNNNGG (a second base sequence: SEQ ID NO: 2) into a promoter, wherein the first DNA fragment and the second DNA fragment are combined as a pair, and in each pair, said first DNA fragment and said second DNA fragment are inserted so that they are arranged sequentially from the 5' end to the 3' end side of said promoter, wherein said first DNA fragment and said second DNA fragment are inserted at the 5'-end side that is upstream to a CCAAT sequence existing in said promoter, or at the 3'-end side that is downstream to a SRE sequence existing in said promoter, and wherein the modified promoter is capable of functioning in a filamentous fungus.

The rejection alleges that "Minetoki et al. teach wherein a plurality of said first DNA fragments and a plurality of said second DNA fragments are inserted (claim 8), and further to wherein the same number of said first DNA fragments and said second DNA fragments are inserted (claim 9)." The rejection further alleges that "Minetoki et al. teach modification of the promoter for the *Aspergillus oryzae* amyB gene...(and) Minetoki et al. teach inserting multiple copies of Region IIIa sequence which contains the second base sequence

'CGGAAATTTAAAGG' inserted in tandem with the Region IIIb sequence which contains the first DNA fragment including the 'CCAATNNNNNN' sequence into the promoter region of a modified vector." (Office Action, p.6).

To anticipate a claim, each and every element of the claim must be found in a single reference. This is discussed in the Manual of Patent Examining Procedure § 2131:

> A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an ipsissimis verbis test, i.e., identity of terminology is not required. In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

The Minetoki et al. reference does not disclose, teach or suggest all the limitations of the instant claims. In particular, nowhere does the Minetoki reference expressly or inherently teach or suggest a modified promoter capable of functioning in a filamentous fungus wherein the first DNA fragment and the second DNA fragment are combined as a pair, **and in each pair, said first DNA fragment and said second DNA fragment are inserted so that they are arranged sequentially from the 5' end to the 3' end side of said promoter**, wherein said **first DNA fragment and said second DNA fragment are inserted at the 5'-end side that is upstream to a CCAAT sequence existing in said promoter, or at the 3'-end side that is downstream to a SRE sequence existing in said promoter**, as claimed.

Applicants point out that Minetoki et al. teach multiple copies of the fragment comprising region III that were introduced into P*agdA* to enhance promoter activity. Applicants point out in particular Figures 1 and 2 and the corresponding legends. Figure 2 is shown below. Figure 2 of Minetoki shows improvement of promoter activity by the introduction of region III. In Figure 2, the location of each conserved element (regions I, II and IIa and IIb) within the promoter region is indicated by a different box pattern. Figure 2 shows the location of the conserved elements (regions I, II, IIIa and IIIb) within the promoter region, as well as the CCAAT box and the TATA box.

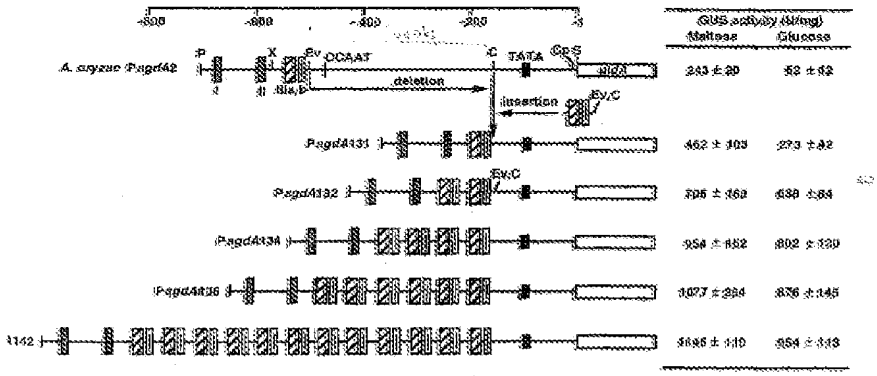


Figure 2 does not show that the first DNA fragment and the second DNA fragment are inserted so that they are arranged sequentially from the 5' end to the 3' end side of said promoter, wherein said first DNA fragment and said second DNA fragment are inserted at the 5'-end side that is upstream to a CCAAT sequence existing in said promoter, or at the 3'-end side that is downstream to a SRE sequence existing in said promoter, as claimed in the present invention.

Accordingly, the Minetoki et al. reference does not anticipate the present invention as claimed. Applicants respectfully request that the foregoing rejection be withdrawn.

Rejection of Claims 1 – 3, 7, 11 – 12, and 15 - 19 Under 35 USC 103(a)

Claims 1 – 3, 11 – 12, and 15 - 19 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Minetoki et al., as applied to the claims above, and further in view of Boel et al. (US Patent 5,536,661). Applicants respectfully traverse the rejection.

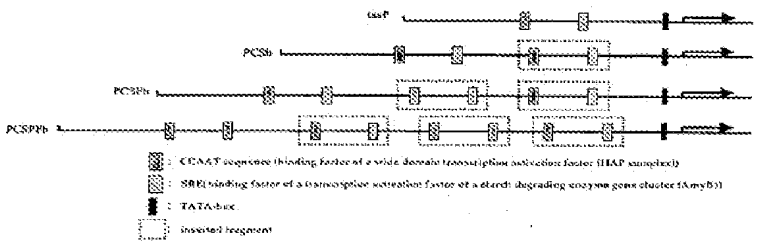
Claim 1 was set forth above.

As discussed above, the Minetoki reference fails to teach all the elements of the invention as instantly claimed. In particular, the Minetoki et al. reference fails to teach or suggest a modified promoter capable of functioning in a filamentous fungus wherein the first DNA fragment and the second DNA fragment are combined as a pair, and in each pair, said first DNA fragment and said second DNA fragment are inserted so that they are arranged sequentially from the 5' end to the 3' end side of said promoter, wherein said first DNA fragment and said second DNA fragment are inserted at the 5'-end side that is upstream to a

CCAAT sequence existing in said promoter, or at the 3'-end side that is downstream to a SRE sequence existing in said promoter, as claimed.

The Boel reference does not cure the defects of the Minetoki reference. Nowhere in the Boel reference is there teaching or suggestion of a modified promoter capable of functioning in a filamentous fungus wherein the first DNA fragment and the second DNA fragment are combined as a pair, where said first DNA fragment and said second DNA fragment are inserted so that they are arranged sequentially from the 5' end to the 3' end side of said promoter, as claimed.

The present inventors have found a pair of sequences capable of enhancing the transcription activity by inserting these sequences into a promoter region of Taka-amylase A. The Taka Amylase A gene of *Aspergillus oryzae* is known to have a high promoter activity, and the present inventors have modified this promoter to obtain a promoter with a higher transcription activity. The present inventors show that in a modified promoter in which a CCAAT sequence and SRE were inserted at the same time, a significant increase in promoter activity was observed, and about four times amylase activity was observed. For example, Applicants show in Examples 7 and 8, beginning on page 39 of the specification, every time a CAAT and SRE sequence is inserted, an increase in the production of amylase was observed:



Promoter	Amylase Activity			
	Starch		Glucose	
	(U/g dry mycelia)	(ratio)	(U/g dry mycelia)	(ratio)
taaP	916	1	25	1
PCSb	4601	5.0	603	24.1
PCSPb	6455	7.0	740	29.6
PCSPPb	7084	7.7	941	37.7

As described in the specification at page 9, FIG. 5 is a table summarizing amylase activities measured in Examples 7 and 8.

The Boel reference does not teach or suggest the present invention as claimed, alone of in combination with the Minetoki et al. reference. The rejection points to claim 1 and Figure 1 to support the argument that Boel et al. teaches modification of the *Aspergillus oryzae* Taka-amylase promoter in the context of a vector expression system expressly designed for expressing target proteins of interest for commercial protein expression. However, nowhere does the Boel et al. reference teach a modified promoter capable of functioning in a filamentous fungus wherein the first DNA fragment and the second DNA fragment are combined as a pair, and in each pair, said first DNA fragment and said second DNA fragment are inserted so that they are arranged sequentially from the 5' end to the 3' end side of said promoter, wherein said first DNA fragment and said second DNA fragment are inserted at the 5'-end side that is upstream to a CCAAT sequence existing in said promoter, or at the 3'-end side that is downstream to a SRE sequence existing in said promoter, as claimed.

Therefore, the teachings of the cited art, when combined, do not result in the claimed invention. Applicants request that the rejection be withdrawn.

CONCLUSION

Early consideration and allowance of the application are earnestly solicited. If a telephone conference with the Applicants' Agent would expedite allowance of this application, the Examiner is urged to contact the undersigned.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105.

Respectfully submitted,

Dated: June 17, 2010

Electronic signature: /James E. Armstrong, IV/
James E. Armstrong, IV
Registration No.: 42,266
EDWARDS ANGELL PALMER & DODGE LLP
P.O. Box 55874, Boston, MA 02205
(202) 478-7370
Attorneys/Agents For Applicant

Customer No. 21874